FEB 2 8 2012

EMPECS MEDICAL DEVICE

CONFIDENTIAL

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K111456

Submitted By: Tianjin Empecs Medical Device Co., Ltd.
Binhe Rd. Hangu Economic Development Zone, Hangu District, Tianjin, 300480, China
Registration Number: 9616530

Contact Person: CQMS Co., Ltd. (Mr. HL Jung)
Room 1301, Gyeonggi Venture Anyang Science University Center, 572-5, Anyang 8-dong, Manan-gu, Anyang-si, Gyeonggi-do, 430-731, Republic of Korea
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Date Summary, Prepared: Feb. 10, 2012

Device Name:

Proprietary Name: Medisign MM1000 Blood Glucose Monitoring System
Medisign MM1100 Blood Glucose Monitoring System
Medisign MM1200 Blood Glucose Monitoring System
Medisign MM1000 Multi Blood Glucose Monitoring System
Medisign MM1100 Multi Blood Glucose Monitoring System
Medisign MM1200 Multi Blood Glucose Monitoring System

Common Name: Glucose Test System

Classification Name: Class II, 21 CFR 862.1345, Glucose Test System
Class I, 21 CFR 862.1660, Quality Control Material

Produce code: NBW, CGA and JJX

Predicate Devices: OneTouch Ultra 2 Blood Glucose Monitoring System (K053529)
OneTouch Ultra Control Solution (K022769)

Device Description:

Medisign MM1000 Blood Glucose Monitoring System, Medisign MM1100 Blood Glucose Monitoring System, and Medisign MM1200 Blood Glucose Monitoring System are basically provided with a blood glucose meter, blood glucose test strips (10T), and a carrying bag including user manual, quick reference manual and log book. Blood glucose test strips (25T, 50T), blood glucose control solutions (Level A, Level B), check strip, diabetes management software, and data

transporting cable are sold separately.

Medisign MM1000 Multi Blood Glucose Monitoring System, Medisign MM1100 Multi Blood Glucose Monitoring System, and Medisign MM1200 Multi Blood Glucose Monitoring System are basically provided with a blood glucose meter, blood glucose test strips (10T), and a carrying bag including user manual, quick reference manual and log book. Disposable lancing device, blood glucose test strips (25T, 50T), blood glucose control solutions (Level A, Level B), check strip, diabetes management software, and data transporting cable are sold separately.

Each box of test strips contains one vial of 10 test strips, one vial of 25 test strips, one vial of 50 test strips, or two vials of 25 test strips. Each test strip contains the following reagent compositions: glucose oxidase (A. Niger) – 2.5 units, redox mediator – 32.3μg and buffer & non-reactant – 50.5μg.

Each box of control solutions (Level A and Level B) contains one vial of aqueous control solution (4ml each): Level A contains 0.11% concentrations of glucose (approximately 120 mg/dL) and Level B contains 0.23% concentrations of glucose (approximately 320 mg/dL).

Only the difference among six blood glucose monitoring systems above is the appearance of the top cases of the meters. Six blood glucose monitoring systems use the same PCB, the same LCD, the same Software, the same test strip, and the same control solution.

Intended Use:

Medisign MM1000 Blood Glucose Monitoring System, Medisign MM1100 Blood Glucose Monitoring System, and Medisign MM1200 Blood Glucose Monitoring System are intended for the quantitative measurement of the concentration of glucose in whole blood drawn from fingertip, palm, and forearm by a single patient (lay user) as an aid in the management of diabetes, is intended for self-testing by persons at home, is for single-patient use only, and should not be shared. It is intended for use the outside of body (in vitro diagnostic use) and not for diagnosis of or screening for diabetes, nor for use on neonates.

The alternative site testing (palm and forearm) in the systems can only be used during steady-state blood glucose conditions.

The Medisign™ MM1000 test strip is to be used with Medisign™ MM1000 Blood Glucose Meter, to monitor glucose concentration of capillary whole blood. Medisign™ MM1000 test strips and associated meter are for use in fingertip, forearm, and palm testing. The strips are intended for self-testing by persons at home, are for single-patient use only, and should not be shared. The strips are not for diagnosis of or screening for diabetes nor for neonatal use.

The Medisign™ MM1100 test strip is to be used with Medisign™ MM1100 Blood Glucose Meter, to monitor glucose concentration of capillary whole blood. Medisign™ MM1100 test strips and associated meter are for use in fingertip, forearm, and palm testing. The strips are intended for self-testing by persons at home, are for single-patient use only, and should not be shared. The strips are not for diagnosis of or screening for diabetes nor for neonatal use.

The Medisign™ MM1200 test strip is to be used with Medisign™ MM1200 Blood Glucose Meter, to monitor glucose concentration of capillary whole blood. Medisign™ MM1200 test strips and associated meter are for use in fingertip, forearm, and palm testing. The strips are intended for self-testing by persons at home, are for single-patient use only, and should not be shared. The strips are not for diagnosis of or screening for diabetes nor for neonatal use.

Medisign MM1000 Multi Blood Glucose Monitoring System, Medisign MM1100 Multi Blood Glucose Monitoring System, and Medisign MM1200 Multi Blood Glucose Monitoring System are intended for the quantitative measurement of the concentration of glucose in whole blood drawn from fingertip, palm, and forearm of diabetic patients by healthcare professionals as an aid in the management of diabetes, and may be used for testing multiple patients in clinical settings. It is intended for use outside of the body (in vitro diagnostic use) and not for diagnosis of or screening for diabetes, nor for use on neonates.
The alternative site testing (palm and forearm) in the systems can only be used during steady-state blood glucose conditions. Only auto-disabling, single use lancing device should be used with this system.

The Medisign™ MM1000 Multi Blood Glucose Test strip is to be used with Medisign™ MM1000 Multi Blood Glucose Meter, to monitor glucose concentration of capillary whole blood. Medisign™ MM1000 Multi Test strips and associated meters are for use in fingertip, forearm, and palm testing. The system is intended for use for multiple-patient use by healthcare professionals in healthcare settings. Only auto-disabling, single use lancing devices should be used with this system to prevent transferring disease by blood. The strips are not for diagnosis of or screening for diabetes nor for neonatal use.

The Medisign™ MM1100 Multi Blood Glucose Test strip is to be used with Medisign™ MM1100 Multi Blood Glucose Meter, to monitor glucose concentration of capillary whole blood. Medisign™ MM1100 Multi Test strips and associated meters are for use in fingertip, forearm, and palm testing. The system is intended for use for multiple-patient use by healthcare professionals in healthcare settings. Only auto-disabling, single use lancing devices should be used with this system to prevent transferring disease by blood. The strips are not for diagnosis of or screening for diabetes nor for neonatal use.

The Medisign™ MM1200 Multi Blood Glucose Test strip is to be used with Medisign™ MM1200 Multi Blood Glucose Meter, to monitor glucose concentration of capillary whole blood. Medisign™ MM1200 Multi Test strips and associated meters are for use in fingertip, forearm, and palm testing. The system is intended for use for multiple-patient use by healthcare professionals in healthcare settings. Only auto-disabling, single use lancing devices should be used with this system to prevent transferring disease by blood. The strips are not for diagnosis of or screening for diabetes nor for neonatal use.

Medisign™ Glucose Control Solutions are for use with Medisign™ Brand Blood Glucose Meters and Medisign™ Test Strips to check that the meter and test strips are working together properly.

Medisign™ Glucose Control Solutions are intended for use by healthcare professionals and people with diabetes mellitus at home. Mesisign™ Glucose Control Solutions are for in vitro diagnostic use.

Comparison to Predicate Devices:

Items	Subject Devices	Predicate Devices
Detection method	Amperometry	Same
Enzyme	Glucose Oxidase (Aspergillus niger)	Same
Mediator	Hexaammineruthenium(III) Chloride	Potassium ferricyanide
Electrod	Carbon electrode	Same
Measurement Range	20~600mg/dL	Same
Hct. Range	30-55%	Same
Reagent Form	Test Strip	Same
Sample Site	Fingertip, Palm, and Forearm	Same
Minimum Sample Size	0.5 ul	1 ul
Measurement Time	5 sec	Same
Memory Capability	300 test results (including date and time)	500 blood glucose or control solution test results
Coding	Auto Coding	Manual Type
Operating Temperature Range	10~40℃	43~111℉
Operating Humidity Range	10-90%	Same
Power	DC 3V CR2032 Lithium battery	Same
External Output	Data transporting cable (USB type)	OneTouch Interface Cable (USB format)
Software	Medisign Link – Diabetes Management Software	OneTouch Diabetes Management Software

Data demonstrating: The clinical data demonstrate the performance of the subject devices well with the laboratory glucose reference test equipment. All predetermined acceptance criteria were satisfied. The data also demonstrate that the subject devices are substantially equivalent to the predicate devices.

Conclusion: The subject devices are substantially equivalent to the following predicate devices:
OneTouch Ultra 2 Blood Glucose Monitoring System (K053529) and
OneTouch Ultra Control Solution (K022769).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

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FEB 2 8 2012

Re: k111456
Trade/Device Name: Medisign MM1000 Blood Glucose Monitoring System
Medisign MM1100 Blood Glucose Monitoring System
Medisign MM1200 Blood Glucose Monitoring System
Medisign MM1000 Multi Blood Glucose Monitoring System
Medisign MM1100 Multi Blood Glucose Monitoring System
Medisign MM1200 Multi Blood Glucose Monitoring System
Medisign Glucose Control Solutions
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, CGA, JJX
Dated: February 10, 2012
Received: February 16, 2012

Dear HL Jung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of

the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111456

Device Name: Medisign™ MM1000 Blood Glucose Monitoring System

Indications for Use:
The system is intended for the quantitative measurement of the concentration of glucose in whole blood drawn from fingertip, palm, and forearm by a single patient (lay user) as an aid in the management of diabetes, is intended for self-testing by persons at home, is for single-patient use only, and should not be shared. It is intended for use the outside of body (in vitro diagnostic use) and not for diagnosis of or screening for diabetes, nor for use on neonates.
The alternative site testing (palm and forearm) in this system can only be used during stead-state blood glucose conditions.

The Medisign™ MM1000 test strip is to be used with Medisign™ MM1000 Blood Glucose Meter, to monitor glucose concentration of capillary whole blood. Medisign™ MM1000 test strips and associated meter are for use in fingertip, forearm, and palm testing. The strips are intended for self-testing by persons at home, are for single-patient use only, and should not be shared. The strips are not for diagnosis of or screening for diabetes nor for neonatal use.

Medisign™ Glucose Control Solutions are for use with Medisign™ Brand Blood Glucose Meters and Medisign™ Test Strips to check that the meter and test strips are working together properly. Medisign™ Glucose Control Solutions are intended for use by healthcare professionals and people with diabetes mellitus at home, Mesisign™ Glucose Control Solutions are for in vitro diagnostic use.

Prescription Use _____	AND/OR	Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K111456

Indications for Use

510(k) Number (if known): K111456

Device Name: Medisign™ MM1100 Blood Glucose Monitoring System

Indications for Use:
The system is intended for the quantitative measurement of the concentration of glucose in whole blood drawn from fingertip, palm, and forearm by a single patient (lay user) as an aid in the management of diabetes, is intended for self-testing by persons at home, is for single-patient use only, and should not be shared. It is intended for use the outside of body (in vitro diagnostic use) and not for diagnosis of or screening for diabetes, nor for use on neonates.
The alternative site testing (palm and forearm) in this system can only be used during stead-state blood glucose conditions.

The Medisign™ MM1100 test strip is to be used with Medisign™ MM1100 Blood Glucose Meter, to monitor glucose concentration of capillary whole blood. Medisign™ MM1100 test strips and associated meter are for use in fingertip, forearm, and palm testing. The strips are intended for self-testing by persons at home, are for single-patient use only, and should not be shared. The strips are not for diagnosis of or screening for diabetes nor for neonatal use.

Medisign™ Glucose Control Solutions are for use with Medisign™ Brand Blood Glucose Meters and Medisign™ Test Strips to check that the meter and test strips are working together properly. Medisign™ Glucose Control Solutions are intended for use by healthcare professionals and people with diabetes mellitus at home, Mesisign™ Glucose Control Solutions are for in vitro diagnostic use.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K111456

Indications for Use

510(k) Number (if known): K111456

Device Name: Medisign™ MM1200 Blood Glucose Monitoring System

Indications for Use:
The system is intended for the quantitative measurement of the concentration of glucose in whole blood drawn from fingertip, palm, and forearm by a single patient (lay user) as an aid in the management of diabetes, is intended for self-testing by persons at home, is for single-patient use only, and should not be shared. It is intended for use the outside of body (in vitro diagnostic use) and not for diagnosis of or screening for diabetes, nor for use on neonates.
The alternative site testing (palm and forearm) in this system can only be used during stead-state blood glucose conditions.

The Medisign™ MM1200 test strip is to be used with Medisign™ MM1200 Blood Glucose Meter, to monitor glucose concentration of capillary whole blood. Medisign™ MM1200 test strips and associated meter are for use in fingertip, forearm, and palm testing. The strips are intended for self-testing by persons at home, are for single-patient use only, and should not be shared. The strips are not for diagnosis of or screening for diabetes nor for neonatal use.

Medisign™ Glucose Control Solutions are for use with Medisign™ Brand Blood Glucose Meters and Medisign™ Test Strips to check that the meter and test strips are working together properly. Medisign™ Glucose Control Solutions are intended for use by healthcare professionals and people with diabetes mellitus at home, Mesisign™ Glucose Control Solutions are for in vitro diagnostic use.

Prescription Use _____	AND/OR	Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K111456

Indications for Use

510(k) Number (if known): K111456

Device Name: Medisign™ MM1000 Multi Blood Glucose Monitoring System

Indications for Use:

The system is intended for the quantitative measurement of the concentration of glucose in whole blood drawn from fingertip, palm, and forearm of diabetic patients by healthcare professionals as an aid in the management of diabetes and may be used for testing multiple patients in professional healthcare settings. It is intended for use the outside of body (in vitro diagnostic use) and not for diagnosis of or screening for diabetes, nor for use on neonates.

The alternative site testing (palm and forearm) in this system can only be used during stead-state blood glucose conditions. Only auto-disabling, single use lancing device should be used with this system.

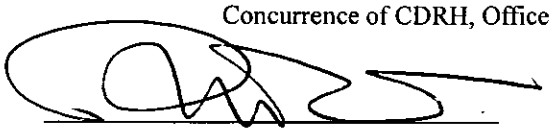
The Medisign™ MM1000 Multi Blood Glucose Test strip is to be used with Medisign™ MM1000 Multi Blood Glucose Meter, to monitor glucose concentration of capillary whole blood. Medisign™ MM1000 Multi Test strips and associated meters are for use in fingertip, forearm, and palm testing. The system is intended for use for multiple-patient use by healthcare professionals in healthcare settings. Only auto-disabling, single use lancing devices should be used with this system to prevent transferring disease by blood. The strips are not for diagnosis of or screening for diabetes nor for neonatal use.

Medisign™ Glucose Control Solutions are for use with Medisign™ Brand Blood Glucose Meters and Medisign™ Test Strips to check that the meter and test strips are working together properly. Medisign™ Glucose Control Solutions are intended for use by healthcare professionals and people with diabetes mellitus at home. Mesisign™ Glucose Control Solutions are for in vitro diagnostic use.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device (OIVD)



Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K111456

Indications for Use

510(k) Number (if known): K111456

Device Name: Medisign™ MM1100 Multi Blood Glucose Monitoring System

Indications for Use:

The system is intended for the quantitative measurement of the concentration of glucose in whole blood drawn from fingertip, palm, and forearm of diabetic patients by healthcare professionals as an aid in the management of diabetes and may be used for testing multiple patients in professional healthcare settings. It is intended for use the outside of body (in vitro diagnostic use) and not for diagnosis of or screening for diabetes, nor for use on neonates.

The alternative site testing (palm and forearm) in this system can only be used during stead-state blood glucose conditions. Only auto-disabling, single use lancing device should be used with this system.

The Medisign™ MM1100 Multi Blood Glucose Test strip is to be used with Medisign™ MM1100 Multi Blood Glucose Meter, to monitor glucose concentration of capillary whole blood. Medisign™ MM1100 Multi Test strips and associated meters are for use in fingertip, forearm, and palm testing. The system is intended for use for multiple-patient use by healthcare professionals in healthcare settings. Only auto-disabling, single use lancing devices should be used with this system to prevent transferring disease by blood. The strips are not for diagnosis of or screening for diabetes nor for neonatal use.

Medisign™ Glucose Control Solutions are for use with Medisign™ Brand Blood Glucose Meters and Medisign™ Test Strips to check that the meter and test strips are working together properly. Medisign™ Glucose Control Solutions are intended for use by healthcare professionals and people with diabetes mellitus at home. Mesisign™ Glucose Control Solutions are for in vitro diagnostic use.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Device (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K111456

Indications for Use

510(k) Number (if known): K111456

Device Name: Medisign™ MM1200 Multi Blood Glucose Monitoring System

Indications for Use:
The system is intended for the quantitative measurement of the concentration of glucose in whole blood drawn from fingertip, palm, and forearm of diabetic patients by healthcare professionals as an aid in the management of diabetes and may be used for testing multiple patients in professional healthcare settings. It is intended for use the outside of body (in vitro diagnostic use) and not for diagnosis of or screening for diabetes, nor for use on neonates.
The alternative site testing (palm and forearm) in this system can only be used during stead-state blood glucose conditions. Only auto-disabling, single use lancing device should be used with this system.

The Medisign™ MM1200 Multi Blood Glucose Test strip is to be used with Medisign™ MM1200 Multi Blood Glucose Meter, to monitor glucose concentration of capillary whole blood. Medisign™ MM1200 Multi Test strips and associated meters are for use in fingertip, forearm, and palm testing. The system is intended for use for multiple-patient use by healthcare professionals in healthcare settings. Only auto-disabling, single use lancing devices should be used with this system to prevent transferring disease by blood. The strips are not for diagnosis of or screening for diabetes nor for neonatal use.

Medisign™ Glucose Control Solutions are for use with Medisign™ Brand Blood Glucose Meters and Medisign™ Test Strips to check that the meter and test strips are working together properly. Medisign™ Glucose Control Solutions are intended for use by healthcare professionals and people with diabetes mellitus at home. Mesisign™ Glucose Control Solutions are for in vitro diagnostic use.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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